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THERAPEUTIC EFFECT OF COPPER SULPHATE VS COMMON SALT (TABLE/COOKING SALT) ON UMBILICAL GRANULOMA IN INFANTS: A COMPARATIVE STUDY

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ABSTRACT: BACKGROUD: Umbilical granuloma is the most common umbilical problem in neonates and young infants. Available treatments of umbilical granuloma includes cauterization with silver nitrate / copper sulphate / Cryo / electro cauterization, use of common salt, alcohol, and granuloma ligation. **OBJECTIVE:** To compare the therapeutic effect of copper sulphate versus common salt (table/cooking salt) on umbilical granuloma in new borns and infants. **METHODS:** This clinical trial was carried out on 98 infants with umbilical granuloma. The neonates and young infants between 2 weeks to 4 months of age brought with umbilical granuloma to the private clinic between September'2007 to November '2014 were enrolled in the study, but 14 infants were excluded out of which 2 infants had congenital heart disease (1 VSD and 1 Tetralogy of Fallot) and remaining 12 infants failed follow up (dropouts). Hence the study included a total of 84 infants. The infants were divided into 2 groups (copper sulphate group = 44, common salt group = 40). The treatment consisted of application of common salt on the lesion twice a day, washed 30 minutes later and repeated for 3 days. Parents of the common salt group were given instruction to treat their infants at home twice a day for three days, but for the copper sulphate group the author has done copper sulphate application on the umbilical granuloma in outpatient clinic. **RESULTS:** 42 out of 44 cases had perfect cure after single local application of copper sulphate and 32 out of 40 cases had perfect cure following twice a day application of common salt for three day course of treatment. **CONCLUSION:** Our data showed that use of copper sulphate application in treating umbilical granuloma is simple, cost effective, curative, safe and superior to common salt application.

KEYWORDS: Umbilical granuloma, Copper sulphate, Common salt, New born infants.

INTRODUCTION: Umbilical granuloma is the most common umbilical abnormality in the neonate.¹ Umbilical granulomas commonly come to attention of parents because of persistent drainage or moisture involving the umbilicus after the cord has dried and separate. The umbilical cord normally separate within 7 to 10 days post partum.² In complete epithelialization over the fibromuscular ring of umbilicus can lead to a beefy red tissue or granulation tissue over the umbilicus. This normal granulation tissue of the resolving umbilical stump of a new born should disappear by the 2nd or 3rd week of the life after proper hygiene. Granulation tissue can over grow at the umbilicus can result in an umbilical granuloma. It contains no nerves and has no feeling^{1,3}. Persistence of the granuloma beyond this time will need some type of therapy.⁴

The aetiology of umbilical granuloma is related to how well the tissue is healing during the drying up process, but the exact cause is unknown.⁵

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Differential Diagnosis:

1. Umbilical Polyp .
2. Urachal Anomaly (Bladder communication).
3. Omphalomesenteric duct anomaly (Bowel communication).
4. Umbilical Mass: a-Ectopic pancreas, b-Umbilical Hernia.

At present the therapeutic options for umbilical granuloma are:

1. Chemical cauterization with silver nitrate or copper sulphate.
2. Topical application of common salt / 82% ethanol or Clobetasolpropionate.
3. Electric cauterization.
4. Cryocauterization.
5. Surgical excision.
6. Double ligature technique.

The conventional method is to do chemical cauterization with 75% silver nitrate stick or solution and copper sulphate., can cause minor burns in the peri-umbilical skin area.⁶ When we consider the advantages and disadvantages of the therapeutic options (Like Silver nitrate application Electric cauterization, Cryocauterization, Surgical excision, Double ligature technique) are associated with increased cost, time consuming, requiring technical skills and their risks (Like bleeding and burns). Whereas common salt application is not associated with the above said complications and easy to apply^{9,10,11,12} In our study we procured copper sulphate commercially available goldsmiths and is also devoid with complications with the said 10 minutes contact time over umbilical granuloma of This study address the successful treatment of umbilical granuloma with a single local application of copper sulphate with less recurrence rate than with that of common salt (Table/ Cooking salt) local application .

MATERIALS AND METHODS: This is a prospective study conducted at a private clinic between September' 2007 to November' 2014. A total of 84 infants (2 weeks to 4 months), both male and female with clinically evident umbilical granuloma who sought treatment in the outpatient department of Paediatrics. The babies enrolled were divided into 2 groups and 44 infants were included in copper sulphate group and 40 infants in common salt group.

The author used the routine commercially available common salt, (Table / cooking salt) and copper sulphate procured from goldsmiths (30 gms copper sulphate for 10 rupees) For the copper sulphate group of infants the author himself involved in the application of powdered copper sulphate as per the procedure described and for the common salt group of infants the first application of a pinch of common salt was done in the outpatient clinic as per the procedure described and the mothers were asked to apply a small pinch of common salt over the umbilical granuloma twice a day for 3 days.

Both the group were evaluated in the outpatient department after 1 week, 3 weeks and 1 month to see the effect of copper sulphate versus common salt on umbilical granuloma and to note any recurrence. The response was graded as:

- a) excellent response - complete regression, no discharge, heal with complete epithelialization
- b) No. response /partial response no regression of umbilical granuloma, persistent umbilical discharge.

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Procedure for copper sulphate / common salt application over umbilical granuloma⁷: Cleanse umbilical area when soiled with urine or faeces. Keep the umbilical area clean and dry. Expose the umbilical area to the air by rolling back the top of the nappy Clean and Dry Skin of any umbilical exudates with sterile gauze and then a pinch of copper sulphate powder/a pinch of common salt (table/ cooking salt) over the umbilical granuloma basing on the chosen group for the infant. Cover the area with sterile gauze and adhesive tapes and held it in place for 10 minutes for copper sulphate group and 30 minutes common salt group. Thereafter, the lesion would be cleansed using cotton ball soaked in boiled water/normal saline. The procedure was repeated twice a day for three consecutive days for common salt group of infants.

RESULTS: Table-1 Age Group distribution (n=84), Table-2 Sex distribution (n=84), Table-3 Sex distribution among copper sulphate group and common salt group (n=84), Table-4 Response to treatment in copper sulphate group (Total Number of patients 44), Table-5 Response to treatment in common salt group (Total Number of patients 40), Table-6 Comparison of response to treatment in the 2 groups at the end of 1st week.

AGE GROUP	NUMBER OF PATIENTS	PERCENTAGE
< 2 Months	69	82.14
2 – 4 Months	15	17.86

Table 1: Age Group distribution (n=84)

SEX	NUMBER OF PATIENTS	PERCENTAGE
MALE	45	53.57
FEMALE	39	46.43

Table 2: Sex distribution (n=84)

SEX	Copper sulphate group(44) NUMBER OF PATIENTS	Common salt group(40)
MALE	25	20
FEMALE	19	20

Table 3: Sex distribution among copper sulphate group and common salt group (n=84)

Response to treatment with single Application at the end of 1 st week of treatment	Number of patients	Percentage
*Excellent response	42	95.5%
Number of patients required 2 nd time copper sulphate application	2	4.5%

Table 4: Response to treatment in copper sulphate group
(Total Number of patients 44)

* Excellent response = umbilicus returned normal

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Response to treatment (With twice a day application for 3 days of treatment) at the end of first week		Number of patients	Percentage
Number of patients with *Excellent response	At the end of first week	22	55
	At the end of 3 rd week	10	25
Number of patients with partial / no response		8	20
Table 5: Response to treatment in common salt group (Total Number of patients 40)			

* Excellent response = umbilicus returned normal

Response to treatment at the end of 1 st week	Copper sulphate group(44) NUMBER OF PATIENTS	%	Common salt group(40)	%
Excellent response	42	95.5	22	55
No response / partial response	2	4.5	18	45
Table 6: Comparison of response to treatment in the 2 groups at the end of 1st week				

DISCUSSION: Umbilical swelling and discharges are common in paediatric practice and may challenge the doctor's diagnostic acumen⁷. The umbilical granuloma is the most common umbilical problem in infants. If umbilical granuloma remains untreated it could ooze and become an irritation for several months⁷. There are many treatment modalities of umbilical-granuloma such as chemical cauterization, electrocauterization, cryocauterization and surgical excision. Though all modalities of treatment had curative effect but each method have advantage and disadvantage. Cauterization with silver nitrate and copper sulphate may cause minor burn of peri-umbilical skin area⁸ which is painful, cryo-cautery is expensive and complex, foul discharge and failure rates were higher with electro-cautery and surgical removal need general anaesthesia and rarely required.

The natural regression of the untreated umbilical granuloma has not being documented. So there is a research for an agent which is without any complication and has a curative effect. In this situation common salt (table/ cooking salt) is a suitable agent for the treatment of umbilical granuloma. Common salt is potent, has no side effect, cost effective and easily available. Encouraged with the experience of others we have also used common salt (Table salt) on our study population.

Total 84 infants were included in our study. Age ranges from 2 weeks to 4months. In literature the incidence of umbilical granuloma is same in both male and female⁴, but in our study slight male preponderance (M: F=1.17:1) noted.

Out of total 84 infants 44 were included in copper sulphate group and 42 infants had excellent response with single application and remaining 2 infants required a second application and found to have excellent response after 1 week. In the second group of total 40 infants included i.e., common salt group 22 infants had excellent response after 1week and 10 infants took 3 weeks to have excellent response. Further 8 infants had no/ partial response at the end of 3 weeks.

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Our study has revealed that a single copper sulphate application for umbilical granuloma resulted in 95.5% (42 out of 44) cure rate and 4.5% (2 out of 44) of infants required a second application of copper sulphate. They too have excellent response (cure) at the end of 1 week after 2nd application. Hence in our study the copper sulphate group had 100% cure rate. Coming to the common salt group 22 infants (55%) out of 40 had excellent response at the end of 1st week and 10 infants (25%) out of 40 had excellent response at the end of 3rd week. But 8 infants (20%) out of 40 from common salt group had no response/partial response.

Umbilical granuloma is minor condition and can be effectively and easily managed by local application of copper sulphate/ common salt (table salt). The umbilical granuloma treated with common salt (table salt) usually clears within three weeks. If a complete cure is not affected within this time surgical advice should be obtained.⁵ But in our study we tried copper sulphate application for the 8 infants with no / partial response in common salt group and followed. All the 8 infants had excellent response at the end of 1 week. The curative mechanism of copper sulphate is believed to be due to chemical cautery over the umbilical granuloma.

The curative mechanism of salt when used in the treatment of umbilical granuloma is thought to be through its desiccant effect and other biologic properties; the high concentration of sodium ion in the area draws water out of the cells and results in shrinkage and necrosis of the wet granulation tissue. However this effect is not so powerful as to cause damage to normal surrounding cornified tissue when applied for a short treatment duration.¹⁰

When we compared the outcome after 1 week, copper sulphate showed better response as compared to common salt (The Chi square value = 16.738, ODDS ratio = 17.18, Confidence interval = 3.64 – 80.89 and p value is < 0.01 (highly significant)) and the difference between the response of copper sulphate and common salt was found to be statistically significant.

Unlike conventional treatment with 75% silver nitrate, which may cause peri-umbilical skin burns and cloth staining and need several applications and should be treated by physician,¹⁰ in our study both copper sulphate and common salt does not have such complications and in our study we found that umbilical granuloma is curable with copper sulphate as well as common salt topical application with no complications in either group but for more number of applications, longer duration of treatment and higher recurrence or failure rate in infants with common salt applications. Further we have encountered parental anxiety, resistance and embracement for common salt application at home.

CONCLUSION: We conclude that application of copper sulphate to the umbilical granuloma is a simple, highly effective and in-expensive form of treatment without any relapse and complications and is superior to common salt in the treatment of umbilical granuloma.

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